State of California—Health and Human Services Agency

California Department of Public Health

Food and Drug Branch – Device Recalls

# California Device Recall Information Sheet

## Fujifilm Healthcare Americas Corporation Recalls FDR Visionary Suite

| Recall Date | Product Description | Recalling Firm | Recall Reason |
|---|---|---|---|
| 5/24/2024 | **FDR Visionary Suite**<br>Intended to generate digital or conventional radiographic images of the skull, spinal column, chest, abdomen, extremities, and other body parts of human anatomies in all routine radiography examinations. Model/Catalog Number: 566-16130-23 566-16130-33 | **FUJIFILM HEALTHCARE AMERICAS CORPORATION**<br>Lexington, Massachusetts | Bolts on the CH-200 tube may rupture due to fatigue failure, causing the tube support to fall, could result in patient injury |

| Recall Class | Product Identification | Distribution | Affected Dates |
|---|---|---|---|
| II | **FDR Visionary Suite**<br>UDI-DI: 04540217052226<br>04540217057450 | 8 Units in California | May 2024 and prior. |

For additional information, please visit the FDA website.

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